Application Number	Application/Control No.	Applicant(s)/Patent Under Reexamination
	10/708,773	YOUSEF ET AL.
	Examiner	**Art Unit**
	Jennifer Kim	1617

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,773	03/24/2004	Abdul Razzaq Yousef	2004-11	2772

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EXAMINER
KIM, JENNIFER M

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
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	Examiner	Art Unit	
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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7 are presented for examination.

Claim 1 is objected to because of the following informalities: The term "acesulfame" appears to be miss-spelled as "acesulfate". Appropriate correction is required.

Specification

The use of the trademark PHARMABURST has been noted in this application. It should be capitalized wherever it appears and be **accompanied by the generic terminology.**

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "basic salt" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 1-7 recite a trade name, PHARMABURST, it is unclear what is the exact content or the ingredient employed since the exact contents are not listed or described in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauwenberge (1992) in view of Martini (U.S. Patent No. 7,182,959 B2) and Norman et al. (U.S.Patent No. 7,118,765 B2).

Cauwenberge teaches safety data on loratadine demonstrate that loratadine does not possess any significant CNS or anticholinergic effects and the side effects. Cauwenberge teaches that loratadine is well tolerated by a wide spectrum of patient populations including the elderly and patients taking a variety of concomitant medications. (abstract).

Cauwenberge does not teach the specific pharmaceutically acceptable carrier such as disintegrant, PHARMABUST, lubricate, talc, lubricant sodium stearyl fumarate, lubricant silicon dioxide, sweetening agent acesulfame potassium, a flavor anise flavor, and mint flavor and the amount of composition dissolute in 45 minutes.

Martini teaches rapidly disintegrating solid dosage form comprising an active substance, a filler a disintegration agent, other usual excipients, like e.g. sweeteners, lubricants, flavors, taste-masking agents, binders, buffering agent, coloring agents, stabilizers and preservatives. (abstract, column 4, lines 4-10). Martini teaches that the dosage form consists essentially of antihistamines, e.g. **loratadine as a active substance**, lubricants as talc, magnesium stearate, sodium stearyl fumarate, silicon dioxide, and acesulfame potassium can be employed as a sweetener and anise flavor and mint flavor can be employed as flavors or taste-masking agents. (column 8, lines 8-26, column 6, lines 65-67). Martini teaches that the dosage form is pleasant to take and once placed into the mouth will disintegrate substantially and instantly without any voluntary action by the patient, such as i.e. chewing. Martani teaches upon disintegration of the tablet, the active ingredient is released and can be swallowed or is absorbed from the buccal cavity, which is advantageous for substance submitted to a high first hepatic metabolism. Martani teaches that the pharmaceutical field, there is a great need for such dosage form because many people are unwilling and/or unable to swallow tablets, capsules and other traditional solid dosage forms. Martani teaches that the dosage form is particularly useful in administration of medicaments to children, debilitated patients, patients who have difficulty swallowing solids and the elderly. (column 1, lines 20-30).

Norman et al. is an actual granted US patent for a novel quick dissolving formulation, PHARMABURST. Norman et al. teach that loratadine is one of a preferred pharmaceutical ingredient that can be employed in such system. (column 12, lines 3-9).

Norman et al. teach that the formulation can be formulated with a lubricant, flavor, color or sweetening agent. (column 12, lines 53-60).

It would have been obvious to one of ordinary skill in the art to formulate loratadine in a novel quick dissolving formulation taught by Norman employing all the ingredients set forth in the claims. One of ordinary skill in the art would have been motivated to make such a modification in order to provide quickly dissolve loratadine well tested to be safe and well tolerated among various populations including elderly. Moreover, Martani teaches that in the pharmaceutical filed, there is a great need for such dosage form because many people are unwilling and/or unable to swallow tablet, capsules and other traditional solid dosage forms. One would have been further motivated to formulate loratadine by combining all the excipients and carriers taught by Martini into novel quick dissolving formulation taught by Norman. There is a reasonable expectation of successfully formulating a novel quick dissolving formulation taught by Norman et al. because all the carriers and excipients that are compatible with loratadine in order to formulate rapidly disintegrating dosage form is well taught by Martini. With regard to the dissolution of at least about 80% of the composition within about 45 minutes set forth in claim 1 would obviously achieved in the obvious composition taught by Cauwenberge as modified by Martini and Norman et al. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claim 3 rejected under 35 U.S.C. 103(a) as being unpatentable over Cauwenberge (1992) in view of Martini (U.S. Patent No. 7,182,959 B2) and Norman et al. (U.S.Patent No. 7,118,765 B2) as applied to claims 1,2 and 4-7 above and further in view of Kreutner et al. (May 2000).

Cauwenberge teaches safety data on loratadine demonstrate that loratadine does not possess any significant CNS or anticholinergic effects and the side effects. Cauwenberge teaches that loratadine is well tolerated by a wide spectrum of patient populations including the elderly and patients taking a variety of concomitant medications. (abstract).

Martini teaches rapidly disintegrating solid dosage form comprising an active substance, a filler a disintegration agent, other usual excipients, like e.g. sweeteners, lubricants, flavors, taste-masking agents, binders, buffering agent, coloring agents, stabilizers and preservatives. (abstract, column 4, lines 4-10). Martini teaches that the dosage form consists essentially of antihistamines, e.g. loratadine as a active substance, lubricants as talc, magnesium stearate, sodium stearyl fumarate, silicon dioxide, and acesulfame potassium can be employed as a sweetener and anise flavor and mint flavor can be employed as flavors or taste-masking agents. (column 8, lines 8-26, column 6, lines 65-67). Martini teaches that the dosage form is pleasant to take and once placed into the mouth will disintegrate substantially and instantly without any voluntary action by the patient, such as i.e. chewing. Martani teaches upon disintegration of the tablet, the active ingredient is released and can be swallowed or is absorbed from the buccal cavity, which is advantageous for substance submitted to a

high first hepatic metabolism. Martani teaches that the pharmaceutical field, there is a great need for such dosage form because many people are unwilling and/or unable to swallow tablets, capsules and other traditional solid dosage forms. Martani teaches that the dosage form is particularly useful in administration of medicaments to children, debilitated patients, patients who have difficulty swallowing solids and the elderly. (column 1, lines 20-30).

Norman et al. is an actual granted US patent for a novel quick dissolving formulation, PHARMABURST. Norman et al. teach that loratadine is one of a preferred pharmaceutical ingredient that can be employed in such system. (column 12, lines 3-9). Norman et al. teach that the formulation can be formulated with a lubricant, flavor, color or sweetening agent. (column 12, lines 53-60).

Above references do not teach the employment of desloratadine.

Kreutner et al. teach that desloratadine is selective histamine H1, antagonist that exhibits qualitatively similar pharmacodynamic activity to its parent, loratadine, but is 2.5 to 4 times more potent orally without behavioral, neurological or autonomic side effects. (abstract).

It would have been obvious to replace desloratadine in the obvious composition of Cauwenberge as modified by Martini and Norman because Kreutner et al. teach that desloratadine is similar to loratadine but 2.5 to 4 times more potent without the side effects. One would have been motivated to make such modification in order to deliver more potent quick dissolving oral desloratadine formulation to elderly or children who

are unable/unwilling to swallow tablets, capsules and other traditional solid dosage forms.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
September 24, 2007